



## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 180

[EPA-HQ-OPP-2012-0710; FRL-9401-5]

#### Boscalid; Pesticide Tolerances

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes tolerances for residues of boscalid in or on multiple commodities which are identified and discussed later in this document.

Interregional Research Project Number 4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

**DATES:** This regulation is effective [*insert date of publication in the Federal Register*].

Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the Federal Register*], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the

#### SUPPLEMENTARY INFORMATION).

**ADDRESSES:** The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2012-0710, is available at <http://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), EPA West Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor

instructions and additional information about the docket available at

*<http://www.epa.gov/dockets>.*

**FOR FURTHER INFORMATION CONTACT:** Lois Rossi, Registration Division

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Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-

7090; email address: *RDFRNotices@epa.gov*.

**SUPPLEMENTARY INFORMATION:**

**I. General Information**

*A. Does this Action Apply to Me?*

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them.

Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

*B. How Can I Get Electronic Access to Other Related Information?*

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at *[http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab\\_02.tpl](http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl)*.

*C. How Can I File an Objection or Hearing Request?*

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2012-0710, in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before [*insert date 60 days after date of publication in the **Federal Register***]. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2012-0710, by one of the following methods:

- *Federal eRulemaking Portal*: <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.
- *Mail*: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

• *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.html>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

## **II. Summary of Petitioned-For Tolerance**

In the **Federal Register** of January 16, 2013 (78 FR 3377) (FRL-9375-4), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 2E8068) by BASF Corporation, 26 Davis Dr, P.O. Box 13528, Research Triangle Park, NC 27709-3528. However, BASF was listed in error. It was the IR-4, 500 College Rd. East, Suite 201W, Princeton, NJ 08540 that petitioned EPA for these tolerances. The petition requested that 40 CFR 180.589 be amended by establishing tolerances for residues of the fungicide boscalid (BAS 510F), 3-pyridinecarboxamide, 2-chloro-*N*-(4'-chloro(1,1'-biphenyl)-2-yl)-, in or on artichoke, globe at 6.0 parts per million (ppm); berry, low growing, subgroup 13-07G at 4.5 ppm; bushberry, subgroup 13-07B at 13 ppm; caneberry, subgroup 13-07A at 6.0 ppm; endive, Belgium at 5.0 ppm; fruit, citrus, group 10-10 at 1.6 ppm; fruit, pome, group 11-10 at 3.0 ppm; fruit, small, vine climbing, except fuzzy kiwifruit, subgroup 13-07F, at 3.5 ppm; oilseed, group 20 at 3.5 ppm; persimmon at 7.0 ppm; turnip, greens at 18.0 ppm; vegetable, bulb group 3-07 at 3.0 ppm; vegetable, fruiting, group 8-10 at 1.2 ppm; and vegetable, root subgroup 1B, except sugarbeet, at 1.0 ppm. The petition also requested the removal of the established tolerances, in or on bushberry, subgroup 13B at 13 ppm; caneberry, subgroup 13A at 6.0 ppm; canola, seed at 3.5 ppm; cotton, undelinted seed at

1.0 ppm; fruit, citrus, group 10 at 1.6 ppm; fruit, pome, group 11 at 3.0 ppm; grape at 3.5 ppm; strawberry at 4.5 ppm; sunflower, seed at 0.6 ppm; vegetable, bulb, group 3 at 3.0 ppm; vegetable, fruiting, group 8 at 1.2 ppm; and vegetable, root, subgroup 1A except sugarbeet, garden beet, radish, and turnip at 1.0 ppm upon approval of the tolerances listed in this unit, since the proposed new tolerances will supersede the existing tolerances. That document referenced a summary of the petition prepared by BASF, the registrant, which is available in the docket, <http://www.regulations.gov>. There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petition, EPA has revised the levels at which some of the tolerances are being established. The reason for these changes is explained in Unit IV.C.

### **III. Aggregate Risk Assessment and Determination of Safety**

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is “safe.” Section 408(b)(2)(A)(ii) of FFDCA defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....”

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for boscalid including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with boscalid follows.

#### *A. Toxicological Profile*

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

In mammals, the primary targets are the liver and the thyroid (indirectly from liver adaptive response). In subchronic and chronic feeding studies in rats, mice, and dogs, boscalid generally caused decreased body weights and body weight gains (primarily in mice) and effects on the liver (increase in weights, changes in enzyme levels and histopathological changes) as well as on the thyroid (increase in weights and histopathological changes). Mode of action studies conducted in rats indicated that boscalid has a direct effect upon the liver and that the thyroid effects are secondary. A reversibility study in rats indicated that both liver and thyroid parameters returned to control values after the animals were placed on control diet. Absolute and/or relative thyroid weights were elevated in rats and dogs, but there were no histopathological changes observed in the thyroid in either mice or dogs.

In a developmental toxicity study in rats, no developmental toxicity was observed in the fetuses at the highest dose tested (limit dose). No effects were noted in the dams in this study. In a developmental toxicity study in rabbits, an increased incidence of abortions or early delivery was observed at the limit dose. There was quantitative evidence of increased susceptibility in the 2-generation reproduction study in rats, where decreases in body weights and body weight gains in male offspring were seen at a dose that was lower than the dose that induced parental/systemic toxicity. There was quantitative evidence of increased susceptibility in the developmental neurotoxicity study in rats, where decreases in pup body weights (PND 4) and body weight gains (PND 1-4) were seen in the absence of any maternal toxicity.

Although there is some evidence indicating increased incidence of thyroid follicular cell adenomas in rats, EPA classified boscalid as “suggestive evidence of carcinogenicity” and has concluded that the endpoint for chronic assessment would be protective of these effects. This is based on the following: The adenomas occurred at dose levels above the level used to establish the chronic population adjusted dose (cPAD), statistically significant increases were only seen for benign tumors (adenomas) and not for malignant ones (carcinomas), the increase in adenomas in females was slight, and there was no concern for mutagenicity.

There was no evidence of neurotoxicity in rats in the acute, subchronic, or developmental studies up to the limit dose. No neurotoxic observations were noted in any of the other studies in any species.

Specific information on the studies received and the nature of the adverse effects caused by boscalid as well as the no-observed-adverse-effect-level (NOAEL) and the

lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at <http://www.regulations.gov> in the document titled “Boscalid Human Health Risk Assessment for a Section 3 Registration of New Uses on Globe Artichoke, Belgium Endive, Persimmon, Greenhouse Grown Tomato Transplants for the Home Consumer Market, and Residential Ornamentals, Landscape Gardens, Fruit Trees and Nut Trees; Plus Crop Group Expansions/Revisions for Bulb Vegetable Group 3-07, Fruiting Vegetable Group 8-10, Citrus Fruit Group 10-10, Pome Fruit Group 11-10, Berry Subgroups 13-07A, B, F, and G, Vegetable Root Subgroup 1B Except Sugar beet, and Oilseed Group 20” on pp. 42-46 in docket ID number EPA-HQ-OPP-2012-0710.

*B. Toxicological Points of Departure/Levels of Concern*

Once a pesticide’s toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern (LOC) to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level – generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD) – and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more



information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see

<http://www.epa.gov/pesticides/factsheets/riskassess.htm>.

A summary of the toxicological endpoints for boscalid used for human risk assessment is shown in Table 1 of this unit.

**Table 1. -- Summary of Toxicological Doses and Endpoints for Boscalid for Use in Human Health Risk Assessment**

Exposure/Scenario	Point of Departure and Uncertainty/Safety Factors	RfD, PAD, LOC for Risk Assessment	Study and Toxicological Effects
Acute dietary (All populations including infants and children and females 13-49 years of age)	No appropriate endpoint attributable to a single dose was identified.		
Chronic dietary (All populations)	NOAEL = 21.8 mg/kg/day UF <sub>A</sub> = 10x UF <sub>H</sub> = 10x FQPA SF = 1x	Chronic RfD = 0.218 mg/kg/day cPAD = 0.218 mg/kg/day	Co-critical chronic rat, carcinogenicity rat, and 1-year dog studies LOAEL = 57-58 mg/kg/day based on liver and thyroid effects
Dermal Short-Term (1-30 days)	Oral study NOAEL = 21.8 mg/kg/day (dermal absorption rate = 15%) UF <sub>A</sub> = 10x UF <sub>H</sub> = 10x FQPA SF = 1x	LOC for MOE = 100	Co-critical chronic rat, carcinogenicity rat, and 1-year dog studies LOAEL = 57-58 mg/kg/day based on liver and thyroid effects
Inhalation Short-Term (1-30 days)	Oral study NOAEL = 21.8 mg/kg/day UF <sub>A</sub> = 10x UF <sub>H</sub> = 10x FQPA SF UF <sub>DB</sub> = 10x	LOC for MOE = 1,000	Co-critical chronic rat, carcinogenicity rat, and 1-year dog studies LOAEL = 57-58 mg/kg/day based on liver and thyroid effects
Cancer (oral, dermal, inhalation)	Classification: "Suggestive evidence of carcinogenicity." The cPAD is considered to be protective of any cancer effects; therefore, a separate cancer assessment is not required.		

FQPA SF = Food Quality Protection Act Safety Factor. LOAEL = lowest-observed-adverse-effect-level. LOC = level of concern. mg/kg/day = milligram/kilogram/day. MOE = margin of exposure. NOAEL = no-observed-adverse-effect-level. PAD = population adjusted dose (c = chronic). RfD = reference dose. UF = uncertainty factor. UF<sub>A</sub> = extrapolation from animal to human (interspecies). UF<sub>DB</sub> = to account for the absence of data or other data deficiency. UF<sub>H</sub> = potential variation in sensitivity among members of the human population (intraspecies).

### *C. Exposure Assessment*

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to boscalid, EPA considered exposure under the petitioned-for tolerances as well as all existing boscalid tolerances in 40 CFR 180.589. EPA assessed dietary exposures from boscalid in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure.

No such effects were identified in the toxicological studies for boscalid; therefore, a quantitative acute dietary exposure assessment is unnecessary.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used food consumption information from the 2003-2008 food consumption data from the U.S. Department of Agriculture's (USDA's) National Health and Nutrition Examination Survey, What We Eat in America, (NHANES/WWEIA). As to residue levels in food, EPA assumed tolerance-level residues and used some percent crop treated (PCT) information as described in Unit III.C.1.iv.

iii. *Cancer.* Based on the data summarized in Unit III.A., EPA has concluded that the chronic endpoint will be protective of potential cancer effects. EPA's estimate of

chronic exposure as described in this unit is relied upon to evaluate whether any exposure could exceed the cPAD and thus pose a cancer risk.

iv. *Anticipated residue and PCT information.* Section 408(b)(2)(F) of FFDCA states that the Agency may use data on the actual percent of food treated for assessing chronic dietary risk only if:

- Condition a: The data used are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain the pesticide residue.
- Condition b: The exposure estimate does not underestimate exposure for any significant subpopulation group.
- Condition c: Data are available on pesticide use and food consumption in a particular area, the exposure estimate does not understate exposure for the population in such area.

In addition, the Agency must provide for periodic evaluation of any estimates used. To provide for the periodic evaluation of the estimate of PCT as required by FFDCA section 408(b)(2)(F), EPA may require registrants to submit data on PCT.

The Agency estimated the PCT for existing uses as follows: Almonds 40%; apples 15%; apricots 25%; blueberries 35%; broccoli 2.5%; cabbage 5%; caneberries 45%; cantaloupes 5%; carrots 15%; cauliflower 5%; celery 2.5%; cherries 45%; cucumbers 5%; dry beans/dry peas 2.5%; garlic 5%; grapes 30%; green beans 5%; green peas 1%; hazelnuts 5%; lettuce 25%; nectarines 15%; onions 20%; peaches 20%; peanuts 1%; pears 15%; peppers 2.5%; pistachios 30%; plums/prunes 5%; potatoes 20%; pumpkins 10%; squash 5%; strawberries 55%; tomatoes 5%; walnuts 1%; and watermelons 25%.

In most cases, EPA uses available data from USDA/National Agricultural Statistics Service (NASS), proprietary market surveys, and the National Pesticide Use Database for the chemical/crop combination for the most recent 6-7 years. EPA uses an average PCT for chronic dietary risk analysis. The average PCT figure for each existing use is derived by combining available public and private market survey data for that use, averaging across all observations, and rounding to the nearest 5%, except for those situations in which the average PCT is less than 1. In those cases, 1% is used as the average PCT and 2.5% is used as the maximum PCT. EPA uses a maximum PCT for acute dietary risk analysis. The maximum PCT figure is the highest observed maximum value reported within the recent 6 years of available public and private market survey data for the existing use and rounded up to the nearest multiple of 5%.

The Agency believes that the three conditions discussed in Unit III.C.1.iv. have been met. With respect to Condition a, PCT estimates are derived from Federal and private market survey data, which are reliable and have a valid basis. The Agency is reasonably certain that the percentage of the food treated is not likely to be an underestimation. As to Conditions b and c, regional consumption information and consumption information for significant subpopulations is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups. Use of this consumption information in EPA's risk assessment process ensures that EPA's exposure estimate does not understate exposure for any significant subpopulation group and allows the Agency to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the Agency. Other than the data available through national food consumption surveys, EPA

does not have available reliable information on the regional consumption of food to which boscalid may be applied in a particular area.

2. *Dietary exposure from drinking water.* The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for boscalid in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of boscalid. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at <http://www.epa.gov/oppefed1/models/water/index.htm>.

Based on the First Index Reservoir Screening Tool (FIRST) and Pesticide Root Zone Model Ground Water (PRZMGW), the estimated drinking water concentrations (EDWCs) of boscalid for chronic exposure assessments are estimated to be 26.4 parts per billion (ppb) for surface water and 697 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For chronic dietary risk assessment, the water concentration of value 697 ppb was used to assess the contribution to drinking water.

3. *From non-dietary exposure.* The term “residential exposure” is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets).

Boscalid is currently registered for the following uses that could result in residential exposures: Golf course turf. Additionally, new residential uses proposed by the registrants Bonide (use on residential fruit and nut trees) and BASF (new uses on residential ornamentals and landscape gardens) were evaluated as part of this action. EPA assessed residential exposure using the following assumptions: All residential

exposures are considered short-term in duration. The residential handler assessment included short-term exposures via the dermal and inhalation routes from treating residential ornamentals, landscape gardens, and trees.

In terms of post-application exposure, there is the potential for dermal post-application exposure for individuals as result of being in an environment that has been previously treated with boscalid. Short-term dermal exposures were assessed for adults, youth 11 to 16 years old, and children 6 to 11 years old. Incidental oral exposure to children 1 to <2 years old is not expected from treated turf because boscalid is registered for use only on golf course turf and proposed for use on residential gardens and trees.

The scenarios used in the aggregate assessment were those that resulted in the highest exposures. The highest exposures for all age groups were associated with only residential post-application dermal exposures, not inhalation exposures, and consist of the following:

- The residential dermal exposure for use in the adult aggregate assessment reflects dermal exposure from post-application activities on treated gardens.
- The residential dermal exposure for use in the youth (11-16 years old) aggregate assessment reflects dermal exposure from post-application golfing on treated turf.
- The residential dermal exposure for use in the child (6-11 years old) aggregate assessment reflects dermal exposure from post-application activities in treated gardens.

Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at

*<http://www.epa.gov/pesticides/trac/science/trac6a05.pdf>.*

4. *Cumulative effects from substances with a common mechanism of toxicity.*

Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider “available information” concerning the cumulative effects of a particular pesticide’s residues and “other substances that have a common mechanism of toxicity.”

EPA has not found boscalid to share a common mechanism of toxicity with any other substances, and boscalid does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that boscalid does not have a common mechanism of toxicity with other substances. For information regarding EPA’s efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA’s website at <http://www.epa.gov/pesticides/cumulative>.

*D. Safety Factor for Infants and Children*

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the Food Quality Protection Act Safety Factor (FQPA SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional SF when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* There was no evidence of increased susceptibility in the rat developmental study as no developmental toxicity was seen at the highest dose tested (limit dose).

There was evidence of increased qualitative susceptibility in the rabbit developmental study as characterized by an increased incidence of abortions or early delivery at the limit dose. It could not be ascertained if the abortions were the result of a treatment-related effect on the dams, the fetuses or both. It was concluded that the degree of concern is low because the increased abortions or early delivery was seen only at the limit dose and the abortions may have been due to maternal stress.

There was evidence of increased quantitative susceptibility seen in the rat 2-generation reproduction study and the developmental neurotoxicity study, in that reduced body weights were seen in the offspring at dose levels where no parental toxicity was observed. However, the degree of concern is low because the dose selected for chronic dietary and non-dietary exposure risk assessments would address the concern for the body weight effects, and the effect was shown to be reversible in the developmental neurotoxicity study.

3. *Conclusion.* EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X for all scenarios, except residential handler inhalation exposure. That decision is based on the following findings:

- i. The toxicity database is complete, with the exception of a subchronic inhalation study. EPA is retaining the 10X FQPA SF for assessing residential inhalation risk to adult applicators.



ii. For the reasons listed in Unit III.D.2., the Agency has concluded that there are no residual uncertainties concerning the potential for prenatal and postnatal toxicity.

iii. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessment assumed tolerances-level residues and was moderately refined using some PCT data. The use of the PCT data for some crops is based on reliable data and will not underestimate the exposure and risk. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to boscalid in drinking water. EPA used similarly conservative assumptions to assess post-application exposure of children. These assessments will not underestimate the exposure and risks posed by boscalid.

#### *E. Aggregate Risks and Determination of Safety*

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the aPAD and cPAD. For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. No adverse effect resulting from a single–oral exposure was identified and no acute dietary endpoint was selected. Therefore, boscalid is not expected to pose an acute risk.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to boscalid from food and water will

utilize 56% of the cPAD for children 1-2 years old, the population group receiving the greatest exposure. Based on the explanation in Unit III.C.3., regarding residential use patterns, chronic residential exposure to residues of boscalid is not expected.

3. *Short-term risk.* Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

Boscalid is currently registered for uses that could result in short-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short-term residential exposures to boscalid. EPA used the dermal exposure scenarios mentioned in Unit III.C.3., in the aggregate assessment because those scenarios resulted in the highest exposures and corresponding lowest MOEs.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded that the combined short-term food, water, and residential exposures result in aggregate MOEs of 290 for adults, 310 for children 6-11 years old, and 690 for youth 11-16 years old. Because EPA's LOC for boscalid is a MOE of 100 or below, these MOEs are not of concern.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

An intermediate-term adverse effect was identified; however, boscalid is not registered for any use patterns that would result in intermediate-term residential exposure. Intermediate-term risk is assessed based on intermediate-term residential exposure plus

chronic dietary exposure. Because there is no intermediate-term residential exposure and chronic dietary exposure has already been assessed under the appropriately protective cPAD (which is at least as protective as the POD used to assess intermediate-term risk), no further assessment of intermediate-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating intermediate-term risk for boscalid.

5. *Aggregate cancer risk for U.S. population.* Based on the data summarized in Unit III.A., EPA has concluded that the cPAD is protective of possible cancer effects. Given the results of the chronic risk assessment, cancer risk resulting from exposure to boscalid is not of concern.

6. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population or to infants and children from aggregate exposure to boscalid residues.

#### **IV. Other Considerations**

##### *A. Analytical Enforcement Methodology*

Adequate enforcement methodology (gas chromatography/mass spectrometry (GC/MS)) is available to enforce the tolerance expression.

The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755-5350; telephone number: (410) 305-2905; email address: *residuemethods@epa.gov*.

##### *B. International Residue Limits*

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs)

established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has not established an MRL for boscalid in/on globe artichoke, Belgian endive, or persimmon.

The tolerances being established by this document for the bulb vegetable group 3-07; the caneberry subgroup 13-07A; the citrus fruit group 10-10; the fruiting vegetable group 8-10; the small, vine climbing fruit, except fuzzy kiwifruit, subgroup 13-07F; and turnip greens align with existing Codex MRLs.

The tolerances being established for the bushberry subgroup 13-07B; the low growing berry subgroup 13-07G, except cranberry and the pome fruit group 11-10; do not align with established MRLs. Harmonization with Codex is not possible because the corresponding commodity group/subgroup tolerance in the United States is higher than the Codex MRL. The higher U.S. tolerance level reflects the likely residues resulting from use in accordance with the approved application rates on the domestic boscalid pesticide label. Reducing the tolerance value to harmonize with Codex levels could result in violations of the tolerance when boscalid is used according to the label.

### *C. Revisions to Petitioned-For Tolerances*

Based on evaluation of the field trial data with the Organization of Economic Cooperation and Development (OECD) tolerance calculation procedure, EPA has modified the proposed tolerance for Belgium endive from 5.0 ppm to 6.0 ppm and the proposed tolerance for persimmon from 7.0 ppm to 8.0 ppm.

The tolerances for the bulb vegetable group 3-07; the caneberry subgroup 13-07A; the citrus fruit group 10-10; the fruiting vegetable group 8-10; the small, vine climbing fruit, except fuzzy kiwifruit, subgroup 13-07F; and turnip greens to align with existing Codex MRLs.

With the establishment of the tolerance for oilseed group 20 the flax, seed; cotton, gin byproducts; and cotton, undelinted seed will be deleted from 40 CFR 180.589(d) since the oilseed group 20 tolerance will supersede these existing tolerances.

In regards to the request for a tolerance for “vegetable, root subgroup 1B, except sugarbeet,” at 1.0 ppm, the petitioner did not submit the data necessary to support establishment of a tolerance for this crop subgroup; therefore, this tolerance is not being established at this time.

### **V. Conclusion**

Therefore, tolerances are established for residues of boscalid in or on artichoke, globe at 6.0 ppm; berry, low growing, subgroup 13-07G, except cranberry at 4.5 ppm; bushberry subgroup 13-07B at 13.0 ppm; caneberry subgroup 13-07A at 10.0 ppm; endive, Belgium at 6.0 ppm; fruit, citrus, group 10-10 at 2.0 ppm; fruit, pome, group 11.10 at 3.0 ppm; fruit, small vine climbing, except fuzzy kiwifruit, subgroup 13-07F at

5.0 ppm; oilseed group 20 at 3.5 ppm; persimmon at 8.0 ppm; turnip, greens at 40.0 ppm; vegetable, bulb, group 3-07 at 5.0 ppm; and vegetable, fruiting, group 8-10 at 3.0 ppm.

In addition, due to the establishment of the new tolerances, the following tolerances are removed as unnecessary from 40 CFR 180.589(a), bushberry subgroup 13B; caneberry subgroup 13A; canola, seed; cotton, undelinted seed; fruit, citrus, group 10; fruit, pome, group 11; grape; strawberry; sunflower, seed; vegetable, bulb, group 3; and vegetable, fruiting, group 8; from 40 CFR 180.589 (d), cotton, gin byproducts; cotton, undelinted seed and flax, seed.

## **VI. Statutory and Executive Order Reviews**

This final rule establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian Tribes. Thus, the Agency has determined that Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA) (15 U.S.C. 272 note).

## VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a “major rule” as defined by 5 U.S.C. 804(2).



**List of Subjects in 40 CFR Part 180**

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: October 29, 2013.

Lois Rossi,

*Director, Registration Division, Office of Pesticide Programs.*

Therefore, 40 CFR chapter I is amended as follows:

**PART 180--[AMENDED]**

1. The authority citation for part 180 continues to read as follows:

**Authority:** 21 U.S.C. 321(q), 346a and 371.

2. In § 180.589:

a. Remove from the table in paragraph (a)(1) the commodities bushberry subgroup 13B; caneberry subgroup 13A; canola, seed; cotton, undelinted seed; fruit, citrus, group 10; fruit, pome, group 11; grape; strawberry; sunflower, seed; vegetable, bulb, group 3; and vegetable, fruiting, group 8.

b. Remove from the table in paragraph (d) the commodities cotton, gin byproducts; cotton, undelinted seed, and flax, seed.

- c. Add alphabetically the following commodities to the table in paragraph (a)(1).

The additions read as follows:

**§ 180.589 Boscalid; tolerances for residues.**

(a) \* \* \*

(1) \* \* \*

Commodity	Parts per million
* * *	* * *
Artichoke, globe	6.0
* * *	* * *
Berry, low growing, subgroup 13-07G, except cranberry	4.5
* * *	* * *
Bushberry subgroup 13-07B	13.0
Caneberry subgroup 13-07A	10.0
* * *	* * *

Endive, Belgium	6.0
Fruit, citrus, group 10-10	2.0
Fruit, pome, group 11-10	3.0
Fruit, small vine climbing, except fuzzy kiwifruit, subgroup 13-07F	5.0
* * *	
Oilseed group 20	3.5
* * *	
Persimmon	8.0
* * *	
Turnip, greens	40.0
* * *	
Vegetable, bulb, group 3-07	5.0
* * *	
Vegetable, fruiting, group 8-10	3.0
* * *	

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